

JUL 21 2008

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Section 05



510(k) SUMMARY IT-V positioning devices

1. BellySTEP™

Submitted by	IT – V Medizintechnik GmbH
	Kranebitterbodenweg 40a 6020 Innsbruck Austria
Contact person	Markus Völp (C.E.O.) Phone: +43/664 4009009
Preparation Date	Feb. 11, 2008
Trade Name	BellySTEP™
Common name	Pelvis and lower extremities immobilization system.
Classification name	Accelerator, Linear, Medical Class 2 devices, 892.5050 IYE
Predicate device	Bellyboard system by SINMED BV
Description of the devices	The BellySTEP™ is made for the positioning of the lower abdomen of a patient. The BellySTEP™ Baseplate enables the use of Inter-changeable inserts. It is made of Polyethylene Foam and covered with artificial leather.
Intended use	Positioning of the lower abdomen of a patient during radiotherapy and diagnostics.
Summary of the technological characteristics of your device compared to the predicate device	The BellySTEP™ is substantially equivalent to the SINMED Bellyboard System in design, construction, and function. The BellySTEP™ is flat and has a similar, generally rectangular-shaped contour, with areas specifically designed for the abdomen, and thighs. The Prone pillow support cushion has a contoured opening so that the patient may rest his/her head comfortably in the prone position during treatment process. The inter-changeable inserts are also designed with an open, contoured cut out region. The patient is positioned over the abdominal cushion such that the belly drops into the cut out region during the radiation therapy session. The BellySTEP™ is constructed in a manner similar to the bellyboard System from SINMED.

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Substantial Equivalence Device	The BellySTEP™ is defined as substantially equivalent (SE) in terms of intended use to the SINMED Bellyboard, manufactured by SINMED BV (Registration number 8030455) and cleared by FDA with K060131.
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	BellySTEP™	SINMED bellyboard system
Intended use	Positioning of the lower abdomen of a patient during radiotherapy and diagnostics.	Positioning of the lower abdomen of a patient during radiotherapy and diagnostics.
Target population	Patients with tumors in the lower-abdomen area.	Patients with tumors in the lower-abdomen area.
Position of the patient	Prone position on this device.	Prone position on this device.
Material	Made of Polyethylene Foam and covered with artificial leather. The PE foam material is commonly used in radiotherapy.	Carbon fiber sandwich construction.
Dimensions	Thick hollow construction with an aperture to place the belly. Flat top-part for positioning the arms and head.	Thick hollow construction with an aperture to place the belly. Flat top-part for positioning the arms and head.
Design / Shape	Ergonomic design for a comfortable position and support of the patient.	Ergonomic design for a comfortable position of the patient. Extra ruler for laser – alignment along the sides of the bellyboard.
Possible adjustments	No adjustments possible, only by using additional cushions like the prone pillow support cushion.	No adjustments possible, only by using additional cushions like the prone-cushion.
Couch fixation	Can be placed at indexed position on the couch.	Can be placed at indexed position on the couch, using fixation strips.
Accessories	Various Inter-changeable inserts and prone pillow to optimize the positioning and comfort of the patient.	Prone cushion for bellyboard to improve the position on the bellyboard.
Compatibility with the environment and other devices	This device can be used both in combination with an CT-scanner and an accelerator.	This device can be used both in combination with an CT-scanner and an accelerator.

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2. HeadSTEP™

Submitted by	IT – V Medizintechnik GmbH
	Kranebitterbodenweg 40a 6020 Innsbruck Austria
Contact person	Markus Völp (C.E.O.) Phone: +43/664 4009009
Preparation Date	Feb. 11, 2008
Trade Name	HeadSTEP™
Common name	Head and neck immobilization systems
Classification name	Accelerator, Linear, Medical Class 2 devices, 892.5050 IYE
Predicate device	Positilt head inclination system by SINMED BV
Description of the devices	The HeadSTEP™ iFRAME based immobilization system guarantees high precision and facile repositioning in routine cranial as well as head and neck immobilization.
Intended use	Fixation and (re)positioning of the head and neck during radiotherapy and diagnostics
Summary of the technological characteristics of your device compared to the predicate device	<p>The HeadSTEP™ is designed to position the head and neck of a patient for diagnostics and radiotherapy and reposition it several times.</p> <p>This is exactly the purpose of the Positilt head inclination system. The same kind of construction and materials are used to reach this. Products from both companies are used for the same kind of radiotherapy treatments. These products from both companies are really competitive systems.</p>
Substantial Equivalence	The HeadSTEP™ is defined as substantially equivalent (SE) in terms of intended use to the SINMED Positilt head inclination system, manufactured by SINMED BV (Registration number 8030455) and cleared by FDA with K060131.

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	HeadSTEP™	SINMED Positilt
Intended use	Fixation and (re) positioning of the head and neck during radiotherapy and diagnostics.	Fixation and (re) positioning of the head and neck during radiotherapy and diagnostics.
Target population	Radiotherapy patients with tumors in head and neck area.	Radiotherapy patients with tumors in head and neck area.
Position of the patient	Lying on a couch in prone or supine position. Shoulders and head are positioned by in a certain position using accessories for an optimized treatment.	Lying on a couch in prone or supine position. Shoulders and head are positioned by in a certain position using accessories for an optimized treatment.
Material	Radio-translucent carbon fiber construction. The skin contact material carbon fiber is exactly the same as those used in the predicate device.	Carbon fiber and acrylic, polyethylene foam.
Dimensions	Square shaped baseplate which follows the patients contours of the head.	Square shaped baseplate which follows the patients contours of the head.
Design / Shape	Flat baseplate on which the thermoplastic mask can be placed. Using a 23-step elevation mechanism, the baseplate can be inclined to change the position of the head.	Flat baseplate on which the thermoplastic mask and various head supports can be placed. Using the Positilt or other accessories, the baseplate can be inclined to change the position of the head.
Possible adjustments	Head can be lifted or inclined by using the 23-step elevation mechanism, without any wedges.	Head can be lifted or inclined by using the blocks and wedges or the Positilt system.
Couch fixation	The aluminum fixation rails connects the baseplate to the couch. The adjustable aluminum rails can be mounted on the baseplate. They allow the baseplate to be locked down in the desired position on the simulator or treatment couch.	The aluminum fixation rails connects the baseplate to the couch. The adjustable aluminum rails can be mounted on all of our baseplates. They allow the baseplate to be locked down in the desired position on the simulator or treatment couch.
Accessories	Foam head supports, which can position the head for an optimized treatment. Thermoplastic mask-material which can be placed on the baseplate with plastic profiles.	Foam head supports, which can position the head for an optimized treatment. Thermoplastic mask-material which can be placed on the baseplate with plastic profiles.

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Compatibility with the environment and other devices	Can be used on all brands of couches in diagnostic and radiotherapy environment.	Can be used on all brands of couches in diagnostic and radiotherapy environment.
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3. BreastSTEP™

Submitted by	IT – V Medizintechnik GmbH
	Kranebitterbodenweg 40a
	6020 Innsbruck
	Austria
Contact person	Markus Völp (C.E.O.) Phone: +43/664 4009009
Preparation Date	Feb. 11, 2008
Trade Name	BreastSTEP™
Common name	Breast and thorax immobilization systems
Classification name	Accelerator, Linear, Medical Class 2 devices, 892.5050 IYE
Predicate Device	Posiboard by SINMED BV
Description of the devices	The BreastSTEP™ enable positioning, repositioning and high comfort in the routine breast and thorax fixation.
Intended use	Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.
Summary of the technological characteristics of your device compared to the predicate device	The SINMED Posiboard is intended to position patients undergoing irradiation treatment in the breast- and lung area. This is exactly the same purpose of the BreastSTEP™. The patient support of the SINMED Posiboard can be inclined for better treatment. This same inclination of the upper body is also possible with the BreastSTEP™. To keep the arms out of the treatment area, the arms are placed above the head. Various arm supports can be fixed on the SINMED Posiboard. This arm support fixation is also possible on the BreastSTEP™. The features of the SINMED Posiboard can all be found on the BreastSTEP™.
Substantial Equivalence Device	The BreastSTEP™ is defined as substantially equivalent (SE) in terms of intended use to the SINMED Posiboard, manufactured by SINMED BV (Registration number 8030455) and cleared by FDA with K060131.

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	BreastSTEP™	SINMED Posiboard
Intended use	Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.	Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.
Target population	Patients with tumors in breast and thorax.	Patients with tumors in breast and thorax.
Position of the patient	Supine position, can be inclined, with arms above the head.	Supine position, can be inclined, with arms above the head.
Material	Carbon fiber sandwich construction, PE Foam, and acrylic. Only non-metal materials are used, like foam, acrylic and carbon fiber sandwich in the treatment area. The skin contact material carbon fiber is exactly the same as those used in the predicate device.	Carbon fiber sandwich construction, PE Foam, and acrylic. Only non-metal materials are used, like foam, acrylic and carbon fiber sandwich in the treatment area.
Dimensions	Optimized dimensions (width) to be CT-scanner compatible.	Optimized dimensions (width) to be CT-scanner compatible.
Design / Shape	Baseplate, with an aperture for placing headsupports. Above the head the arms can be placed by using various armsupports.	Baseplate, with an aperture for placing headsupports. Above the head the arms can be placed by using various armsupports.
Possible adjustments	0-20 degrees inclination possible.	0-25 degrees inclination possible.
Couch fixation	The BreastSTEP™ is fixed onto the couch using indexing bars.	The Posiboard is fixed onto the couch with fixationstrips.
Accessories	Various headsupports for a comfortable patient positioning. Various armsupports for patient positioning.	Various headsupports for a comfortable patient positioning. Various armsupports for patient positioning.
Compatibility with the environment and other devices	Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy.	Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy.

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4. ProSTEP™

Submitted by	IT – V Medizintechnik GmbH
	Kranebitterbodenweg 40a 6020 Innsbruck Austria
Contact person	Markus Völp (C.E.O.) Phone: +43/664 4009009
Preparation Date	Feb. 11, 2008
Trade Name	ProSTEP™
Common name	Pelvis and lower extremities immobilization systems
Classification name	Accelerator, Linear, Medical Class 2 devices, 892.5050 IYE
Predicate device	Combifix by SINMED BV
Description of the devices	The ProSTEP™ was designed to improve the accuracy of the positioning of the hip and the lower extremities.
Intended use	Positioning of hip and lower extremities of a patient for radiotherapy
Summary of the technological characteristics of your device compared to the predicate device	The SINMED Combifix is intended for positioning and immobilization of pelvis and lower extremities. The ProSTEP™ is a system with which the pelvis and lower extremities are positioned in the same way as with the SINMED Combifix. Both devices are exactly the same in terms of intended use and technical characteristics.
Substantial Equivalence Device	The ProSTEP™ is defined as substantially equivalent (SE) in terms of intended use to the SINMED Combifix, manufactured by SINMED BV (Registration number 8030455) and cleared by FDA with K060131.

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	ProSTEP™	SINMED Combifix
Intended use	Positioning of hip and lower extremities of a patient for radiotherapy.	Positioning of hip and lower extremities of a patient for radiotherapy.
Target population	Patients undergoing irradiation treatment in pelvis or lower extremities.	Patients undergoing irradiation treatment in pelvis or lower extremities.
Position of the patient	Supine position.	Supine position.
Material	Carbon fiber sandwich construction or plastic (PE-Foam) devices.	Carbon fiber sandwich construction or plastic (acrylic and PE-Foam) devices.
Design	Baseplate on which the hip and lower extremities of the patient can be positioned by using a KneeSTEP and FeetSTEP system.	Baseplate on which the hip and lower extremities of the patient can be positioned by using a Kneefix or Feetfix.
Possible adjustments	These devices can be adjusted to optimize the fit for the patient. Individual adjustment can be reached by changing distances.	These devices can be adjusted to optimize the fit for the patient. Individual adjustment can be reached by changing distances.
Couch fixation	Baseplate can be positioned on the couch on indexed positions.	Baseplate can be positioned on the couch on indexed positions.
Accessories	N. a.	Repovac vacuum cushions. Multi Purpose Support Cushion
Compatibility with the environment and other devices	The ProSTEP™ can be used both in the diagnostic and treatment environment, due to the materials and construction chosen.	The Combifix system can be used both in the diagnostic and treatment environment, due to the materials and construction chosen.

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5. WingSTEP™

Submitted by	IT – V Medizintechnik GmbH
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Contact person	Markus Völpl (C.E.O.) Phone: +43/664 4009009
Preparation Date	Feb. 11, 2008
Trade Name	WingSTEP™
Common name	Breast and thorax immobilization systems
Classification name	Accelerator, Linear, Medical Class 2 devices, 892.5050 IYE
Predicate Device	PET-armsupport by SINMED BV
Description of the devices	The WingSTEP™ enable positioning, repositioning and high comfort in the routine breast and thorax fixation.
Intended use	Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.
Summary of the technological characteristics of your device compared to the predicate device	<p>The SINMED PET-armsupport is intended to position patients undergoing irradiation treatment in the breast- and lung area. This is exactly the same purpose of the WingSTEP™.</p> <p>To keep the arms out of the treatment area the SINMED PET-armsupport place the arms above the head. This positioning of the arms above the head to achieve more space around the breast- and lung area is also the exact intended use of the WingSTEP™.</p>
Substantial Equivalence Device	The WingSTEP™ is defined as substantially equivalent (SE) in terms of intended use to the SINMED PET-armsupport, manufactured by SINMED BV (Registration number 8030455) and cleared by FDA with K060131.

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	WingSTEP™	SINMED PET-armsupport
Intended use	Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.	Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.
Target population	Patients with tumors in breast and thorax.	Patients with tumors in breast and thorax.
Position of the patient	Supine position with arms above the head.	Supine position with arms above the head.
Material	Acrylic construction, PE foam. Only non-metal materials are used, like foam and acrylic in the treatment area.	Acrylic construction, PE foam. Only non-metal materials are used, like foam and acrylic in the treatment area.
Dimensions	Optimized dimensions (width) to be CT-scanner compatible.	Optimized dimensions (width) to be CT-scanner compatible.
Design / Shape	Baseplate, with an aperture for placing headsupports. Above the head the arms can be placed by using armsupports.	Baseplate, with an aperture for placing headsupports. Above the head the arms can be placed by using armsupports.
Possible adjustments	No adjustments possible.	No adjustments possible.
Couch fixation	The WingSTEP™ is fixed onto the couch using indexing bars.	The PET-armsupport is fixed onto the couch with fixationstrips.
Accessories	Various headsupports for a comfortable patient positioning. Armsupports for patient positioning.	Various headsupports for a comfortable patient positioning. Armsupports for patient positioning.
Compatibility with the environment and other devices	Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy.	Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy.

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6. iCAST™

Submitted by	IT – V Medizintechnik GmbH
	Kranebitterbodenweg 40a 6020 Innsbruck Austria
Contact person	Markus Völz (C.E.O.) Phone: +43/664 4009009
Preparation Date	Feb. 11, 2008
Trade Name	iCAST™
Common name	Thermoplastic immobilization system
Classification name	Accelerator, Linear, Medical Class 2 devices, 892.5050 IYE
Predicate Device	Raycast Thermoplastics by ORFIT Industries
Description of the devices	The iCAST™ Thermoplastic is a non-sticky low temperature thermoplastic sheet material for the production of immobilization masks (head, head/neck) for patients undergoing radiation therapy treatment.
Intended use	Thermoplastic materials are used to retain and reproduce a patient's position during radiation therapy.
Summary of the technological characteristics of your device compared to the predicate device	ORFIT has registered this product in 1999. ORFIT is one of our distributors. We want to register this product under our own name. So the product we want to register is exactly the same as registered by ORFIT in 1999. The material, the intended use, etc. have not changed since then. Therefore a comparison seems to be not necessary.
Substantial Equivalence Device	The thermoplastic is defined as substantially equivalent (SE) in terms of intended use to the ORFIT Raycast thermoplastic material, manufactured by ORFIT (Registration number 9613183) and cleared by FDA with K991319.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2008

Ms. Cornelia Damsky
Regulatory Consultant
IT V MEDIZINTECHNIK GMBH
56 Westcott Road
STAMFORD CT 06902

Re: K081218

Trade/Device Name: IT-V Positioning Devices: BellySTEP™, HeadSTEP™, BreastSTEP™, ProSTEP™, WingSTEP™, and iCAST™

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: II

Product Code: IYE

Dated: April 11, 2008

Received: May 1, 2008

Dear Ms. Damsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 04



Indications for Use

510(k) Number K081218

Device Name:

IT-V positioning devices:

1. BellySTEP™
2. HeadSTEP™
3. BreastSTEP™
4. ProSTEP™
5. WingSTEP™
6. iCAST™

Indications for Use:

1. BellySTEP™ The function of the BellySTEP™ is for positioning of the lower abdomen of a patient during radiotherapy and diagnostics.
2. HeadSTEP™ The function of the HeadSTEP™ is for fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.
3. BreastSTEP™ The function of the BreastSTEP™ is for positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.
4. ProSTEP™ The function of the ProSTEP™ is for positioning of hip and lower extremities of a patient for radiotherapy.
5. WingSTEP™ The function of the WingSTEP™ is for positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.
6. iCAST™ The function of the iCAST™ thermoplastic materials are for use in retaining and reproducing a patient's position during radiation therapy.

Prescription Use: Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K081218